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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,704	04/14/2006	Thomas J Gardella	0609.5140000/TJS/PAC	5389

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EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
01/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,704	GARDELLA ET AL.	
	Examiner	Art Unit	
	David Lukton	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *2-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' election of Group I (claim 1) is acknowledged. Also acknowledged is applicants' initial attempt to comply with the "election of species" requirement. In response thereto, applicants have elected type I osteoporosis as the condition to be treated, and "parenteral" as the route of administration in the elected method. However, in response to elect a specific peptide, applicants have instead elected a genus of not inconsiderable size. As it happens, the subgenus which applicants have elected contains no fewer than 1296 different peptides. Election is required of a specific peptide, in which each of the amino acids is uniquely identified. (Also, if a lactam bridge is not specified, it will be assumed to be absent).

As for the route of administration, "parenteral" is also a subgenus of sorts. This would include subcutaneous administration as well as transcutaneous, intramuscular, intravenous, or pulmonary administration and intranasal insufflation as well. Thus, election is required of a more specific route of administration.

Regarding applicants traversal, applicants have made reference to an undefined "ABsp" and a "Bsp". The issue here is that some of the peptides may be known in the prior art for treating bone-related disorders, and that in the absence of a restriction, applicants could add various claims which recite specific carriers (e.g., saline, propylene glycol, polyethylene glycol, an oil of vegetable origin, a hydrogenated naphthalene, a bile salt, an

acylcarnitine, lactose or dextran, a sugar, calcium stearate, magnesium stearate, or pre-gelatinated starch). Applicants could then argue that the examiner bears the obligation of finding references for every one of the carriers which applicants might choose to recite, and to provide a justification for combining each with the peptide. While this might not impose an insurmountable burden, it can substantially delay the process of discovering that which is novel. In addition, applicants could add claims that recite various forms of the composition, e.g., tablets, oils or powders. Moreover, applicants were given the opportunity to elect Group 3, which includes the peptides of claim 1; and applicants have chosen not to take this option. Notwithstanding the foregoing, it is very unlikely to be the case (ultimately) in which claim 1 is novel, but at the same time, that claims 3 and 5-11 are not novel, at least to the extent that these claims (3 and 5-11) are limited to the peptides of claim 1. Accordingly, in the event that claim 1 is determined to be novel, in current form or in amended form, it is likely that Group 3 would be rejoined therewith.

Applicants have also argued that a search for the Group 1 peptides would lead to the Group 2 peptides. However, this assertion is entirely false.

Applicants are held to be not fully responsive to the previous Office action.

. . . .

Applicants are required under 35 U.S.C. §121 to elect disclosed species (as follows) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally

held to be allowable.

Election of each of the following is required (the lettering begins with "d" to avoid conflict with the previous lettering system:

d) a specific and fully defined peptide (or a salt thereof);

e) one of the following: (i) the route of administration is intramuscular, (ii) the route of administration is intravenous, (iii) the route of administration is intranasal, (iv) the route of administration is subcutaneous, (v) the route of administration is transcutaneous, (vi) the route of administration is parenteral but is not, at the same time, intramuscular or intravenous or intranasal or subcutaneous or transcutaneous.

. . . .

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

DAVID LUKTON, PH.D.
PRIMARY EXAMINER